EXHIBIT 6

From: Kammerer, Gene [ETHUS]
Sent: Mon, 01 May 2006 16:11:00 GMT
To: Fournier, Herve [BuSFR] <HFOURNIE@jnjfr.jnj.com>
Subject: RE: GY :* * * URHENT * * * French STANDARD ON TVT & Meshes (COMMENTS REQUIRED) - Please Forward To The Appropriate Person -

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Herve,

Para 4. Erosions should include "dehiscence" under section *e - other erosions delayed/at distance.* That is, failure of the incision to close over the implant. Erosion is difficult to identify as a consequence of the material. It more than usual is a consequence of the technique of the surgeon and some times in connection with the material. Good indications of the potential for erosion are covered in section 5.3 Biological evaluation. **5.3.2.3 Tests of implantation** *f.) Evaluation histological* ...thickness and density of fibrous reaction developed with the center and in periphery of the implant, contraction, of the implant, folds. Evaluation of the tissue in growth into the pores of the implant will indicate the compatibility of the implant with the tissue, and the likeliness, or potential for the implant to be rejected by the body. Continued or constant inflammation of the tissue associated with the implant will indicate potential erosion caused by the material. Encapsulation of the material by the tissue should be identified as an evaluation aspect as well. If the pores of the implant are not compatible with the tissue surrounding it, it will be encapsulated not integrated. Therefore, identifying the difference between integration of tissue into and through the implant is critical and different than encapsulation, where the body seals the implant off.

Para 5.2.2 **particles Release (fraying)** describes a method of measurement of particles which may be released from the implant while implanted the body. Generally, when we talk about fraying as associated with urethral slings or pelvic floor support materials made from meshes, we are describing loss of pieces of the device as it is manipulated during insertion. Our tests are done on a weight loss basis. We do not count particles or observe particle size. Briefly, the mesh is weighed, then stretched to a specific tension or % elongation, then weigh again and the difference in weight is reported as the % particle loss. We have no specification or limitation. The data is collected for information purposes only. It would not be proper to add a specification amount of acceptable loss. For example, a mesh weighing 2.0 grams is inserted into the body. It is determined that during insertion 0.4% of the mesh is dislodged. So, 0.008 grams of the mesh is in the body but not attached to the main structure. What does that mean? I think it means nothing from a safety, clinical or functional aspect of the product. Therefore, the particle loss test is not relevant, unless it can be identified that the material which "Frays" has some impact on the safety, clinical outcome or functionality of the product, and the test should be either eliminated or better defined against this criteria. The later task would be the responsibility of the AFNOR WG1.

Gene
-----Original Message-----
From: Fournier, Herve [BuSFR]
Sent: Friday, April 28, 2006 7:43 PM
To: Ciarrocca, Scott [ETHUS]; Smith, Dan [ETHUS]; Kammerer, Gene [ETHUS]
Cc: Soulier, Laurent [JNJCH]; Gauthier, Eric [JNJCH]; Buchon, Xavier [ETHFR]; Arnaud, Axel [ETHFR]; Hojnoski, Patricia [ETHUS]; Gadot, Harel [JNJIL]; Fournier, Herve [BuSFR]
Subject: GY :* * * URHENT * * * French STANDARD ON TVT & Meshes (COMMENTS REQUIRED) - Please Forward To The Appropriate Person -
Importance: High
Sensitivity: Confidential
Dear all,

Please find here attached the translation (**PrNF S92B 2006 03 AFNOR TRANSLAT.doc**) of the first draft of the French standard (**pr_nf_s92b_gt1[1]_WG1_[20060324].pdf**) concerning TVT-like slings and meshes prepared by AFNOR WG1 preclinical tests (French standards organization)

The English translation I try to perform is in a panel of 3 columns (French / English / Comments)
Each page of the French PDF AFNOR prNF document is copied in column 1 of Word document AND marked off in the top in blue cells.

You can go direct to the important sections withhypertext-links close to thesymbol:

Click in the boxes in the panel :
IMPORTANT SECTION
to reach 5 Pre-clinical characterization and tests

5.2.2 particles Release (fraying)
to reach this sub paragraph 5.2.2.

5.3 Biological EVALUATION
to reach this sub paragraph 5.3.

I need your comments on § 4 and 5 and particularly on sub paragraph **5.2.2** (yellow section) and if possible **a rational to thwart the willing from our competitors** (PORGES, CL-MEDICAL and others ...) **and AFSSAPS** (our Competent Authority) **concerning this fraying issue** (this will be very difficult) . Have you studies on the no risk on the particle releases ?
(feel free to fill-in the 3rd column of the panel)

Please note that CL-MEDICAL will prepare an additional test of **fraying under stress**.
Could you please let me know what the maximum tensile strength to apply on our devices?
What is the nominal tensile strength applied in normal clinical use?
Could you please let me know what limit we could agree?

What are your recommendations on *Chronic toxicity* and *Carcinogenicity/ Cancerogenicity* sections and paragraph 7.

If possible could you please provide comments on the other section too § 4 § 5.3 ?

here is an extract of the panel

5 Pre-clinical characterization and tests

5.1 Mechanical evaluation:

Tensile strength (breaking strength and elasticity)
Tear strength started (Started tear strength)
Suture strength (Strength to suturing)
Bursting strength
Stiffness and flexibility/pliability

5.2 Physic evaluation

5.2.1 Plan

Thickness
Surface masse Mass per surface (kg/m2)
Porosity (size of the pores and average porosity)
Size of the wire (Wire grist)
Wire strength (Tensile strength of the wires)
Release of particles (Fraying)
Surfaces property (Properties of surfaces)

5.2.2 particles Release (fraying)

a) Small equipment:
- Cleaned and dried "Bécher" glasses, rinsed with alcohol and then with water for intravenous perfusion.
- Ringer's solution (quantity to be determined according to the sample)
- Bain-Marie (37 +-2°C) with agitator (stirring machine)
- Particle counter (ex: HIAC, VersaCount LV)

Principle of the counter:
Optical sensor with measurement range of particles from 2 to 200 µm.
A transfer pump aspires the liquid in the measuring cell by the intermediary of a tube/pipe (inert material eg: Teflon).
The apparatus must guarantee a stable flow of aspiration approx. 25 ml/mn (ex: +/- 5%).
The liquid is illuminated while passing in the measuring cell by a laser beam; a photodetector faces the laser source and

measures luminous energy crossing the cell.
When a particle cuts the beam partly measured energy decreases.
The variation of light intensity is converted by the photodetector into electric power whose amplitude is a function of the detected size of the particles.
The apparatus compares the amplitude of the signal with calibrated thresholds and dimensions the particle, and then this information is stored and sorted by range of sizes of particles.

b) Implementation of counting:
- To place the sample in the "Bécher" glass (without contaminating it, clean room, hood etc...)
- To pour the appropriate quantity of Ringer's solution in the "Bécher" glass; to close the "Bécher" glass.
- To place in the Bain-Marie with mechanical agitator (stirring machine) speed 2 to 3 stroke/minutes during 8 hours (by ex +/- 30 minutes)
- To check that the level of the bain-Marie is over the top of the solution to be tested
- To put under the same conditions a "blank" of constituting of 200 ml of Ringer's solution in a "Bécher" glass.

c) *Measurement:*
After eight hours to immerse the removal pipe in the "Bécher" glass and to launch measurement.
Between each "Bécher" glass made a rinsing with water for intravenous perfusion.

d) *End:*
Cleaning and rinsing drying of the materials.
etc.. *(please go in the word document for continuation)*

I apologize for the delay

Best regards,
Hervé FOURNIER Pharm.D
Regulatory Affairs Manager
ETHICON SAS
Tel +33 1 55 00 26 68
Fax +33 1 55 00 28 34
hfournie@jnjfr.jnj.com

-----Message d'origine-----
De : Fournier, Herve [BuSFR]
Envoyé : jeudi 23 mars 2006 15:41
À : Hojnoski, Patricia [ETHUS]; Ciarrocca, Scott [ETHUS]; Smith, Dan [ETHUS]
Cc : Brunel, Pascale [BuSFR]; Labedan, Francoise [BuSFR]; Soulier, Laurent [JNJCH]; Negri, Blandine [JNJCH]; Gauthier, Eric [JNJCH]; Buchon, Xavier [ETHFR]; De Lacroix, Bruno [ETHUS]; Arnaud, Axel [ETHFR]
Objet : TR: FW: AFNOR (ISO) Organization - Request
Importance : Haute
Critère de diffusion : Confidentiel

Dear all,

As you probably know, AFNOR (French standardization organization) prepares a standard on SUI tapes and prolapsus repair meshes implanted by vaginal ways;

Manufacturers, Surgeons (KOL) and AFSSAPS are gathered in a TF S92B, which is split in two working groups (WG) to write the draft of the standard which is scheduled to be to CEN in the next forthcoming years.

- **(WG1) - Preclinical requirements**

WG will deal with mechanical tests and all tests prior clinical requirements (biological, toxicity and so on, etc.).
Dr Cosson (coordinator - Hospital of Lille)
M Therin (coordinator - Sofradim)
M Lespinasse (Porges)
M Marie (Tyco)
M Simon (AMS)
M Boucherat (Surgical)
M Lacaux (Cook)
M Beraud (Abiss)

Mme Rufach (LNE)
M Goria (CL Medical)
M Petzol (Bard France)
M Galand (Bard France)
M Mejean (Bard France)
Mme Touzart (Textile HI-TEC)
M Houard (Textile HI-TEC)
M Fournier (Ethicon)
M Wiecek (Aspide Medical)

- **(WG2) - Clinical requirements WG.**

Dr Hermieu (coordinator)
Dr Arnaud (coordinator - Ethicon)
M Becker (Sofradim)
M Chatillon (Tyco)
M Goria (CL Medical)
M Olin (Cook)
M Gendre (ALM)
M Giquel (Textile Hi-Tec)
M Buchon (Ethicon)
M Mejean (Bard France)
M Wiecek (Aspide Medical)
Mme Lefevre (Cousin)
Mme Molitor (Cousin)
M Fraslin (AFSSAPS)
Dr Debodinance (Hospital)
Mme Congard-Chassol (Porges SAS)

Here is a quick frame of the standard.

Frame of the standard defined by the WG1 (pre-clinical evaluation)
Implants of support and/or reinforcement set up by vaginal way
Pre-clinical and clinical evaluations

Foreword
1 Scope
2 Normative references
3 Terms and definitions

4 Classification and materials
4.1 Raw materials: synthetic and/or biological
4.2 Structure: manufacturing and assembly methods
4.3 coating

5 Evaluation:
5.1 Mechanical evaluation:
§ Tensile strength (strength at breaking and elasticity)
§ Started tear strength
§ Strength to suturing
§ Burst strength
§ Stiffness and flexibility/pliability
5.2 Physic evaluation:
§ Thickness
§ Mass per surface (kg/m2)
§ Porosity (size of the pores and average porosity)
§ Wire grist
§ Tensile strength of the wires
§ Fraying / release of the particles
§ Properties of surfaces
5.3 Biological evaluation: biological evaluation of the medical devices (Implantation/animal studies)

§ Absorption
§ Materials of biological origin
§ Fraying/release of the particles
5.4 clinical evaluation and data

6 Information supplied by the manufacturer

Annex
Bibliography

Next meeting is planed on next Friday 24 March 2006

I received the homework from our colleagues of the WG1 last 03/21 in French. Please find those ones in the zip file attached **"S92B 2006 03 24.zip"**

Which one include as follows
Suggestions on paragraph 4 of the standard:
Michel_COSSON_mail_[20060321].pdf +
attachement_to_Michel_COSSON_mail[prothcosson.doc].pdf

Suggestions on paragraph 5.1, 5.2 of the standard and Fraying:
William_WIECEK_mail_[20060321].pdf +
attachement_to_William_WIECEK_mail[porosité].pdf

Suggestions on paragraph 2, 5.1, 5.2 and 5.3 of the standard :
Michel_THERIN_mail1_[20060321].pdf +
attachement_to_Michel_THERIN_mail1[Evaluation physico-mécanique renforts voie basse1.doc].pdf
and
Michel_THERIN_mail2_[20060321].pdf +
attachement_to_Michel_THERIN_mail2[Evaluation biologique renforts voie basse.doc].pdf

The time frame is unfortunately too short to perform the translation in English language of the all texts by this evening.

Most of the referenced standards in the texts are ISO / and also ASTM ones.
Please refer to the document attached: **"Frame of the standard defined by the WG1 ISO.pdf"**

Concerning this issues could you please let us know if you have a position paper.

Best regards,
Hervé FOURNIER Pharm.D
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-----Message d'origine-----
De : Brunel, Pascale [BuSFR]
Envoyé : lundi 20 mars 2006 12:02
À : Fournier, Herve [BuSFR]
Objet : TR: FW: AFNOR (ISO) Organization - Request

Bien cordialement,

Pascale Brunel
business services - produits de santé
Affaires Pharmaceutiques & Réglementaires
(01 55 00) 20 78 - bureau P2 267

-----Message d'origine-----
De : Buchon, Xavier [ETHFR]
Envoyé : vendredi 29 avril 2005 19:57
À : Ciarrocca, Scott [ETHUS]; Brunel, Pascale [BuSFR]
Cc : Toddywala, Ronnie [ETHUS]
Objet : Re: FW: AFNOR (ISO) Organization - Request

Thank you Scott. I do understand that we can not obtain all the info very easily and that some of them may be sensitive to share.
You re right in saying that we talk about materials before final products and we may assume that the limits are sometimes difficult to find when replying to such request.
I m sure they are willing in fact to receive a reply combining both.
We are looking forward your next update
Thanks again
Xavier

-----Original Message-----
From: Ciarrocca, Scott [ETHUS] <SCiarro2@ETHUS.JNJ.com>
To: Buchon, Xavier [ETHFR] <XBUCHON@jnjfr.jnj.com>; Brunel, Pascale [BuSFR] <PBRUNEL@jnjfr.jnj.com>
CC: Toddywala, Ronnie [ETHUS] <RToddywa@ETHUS.JNJ.com>
Sent: Thu Apr 28 12:58:58 2005
Subject: RE: FW: AFNOR (ISO) Organization - Request

Xavier / Pascale -

Looking into finding a way to give you specifics - it is unfortunately not straightforward to obtain all of this. To be clear, we are talking about PROLENE and GYNEMESH* PS (PROLENE SOFT) - the implantable materials, NOT the TVT and PROLIFT devices themselves - correct? Details on what was done to support release of the TVT, TVT-O, and PROLIFT products is more sensitive and really is best described by a summary of our Design And Development / Design Control Process.

Regarding EU release / CE Mark, for implantable materials, I know of no additional tests or evaluations that are required above that which we would need to perform for the US Market. Of course we need our ISO certification but anyone who produces CE-marked product will generally have this.

-----Original Message-----
From: Buchon, Xavier [ETHFR]
Sent: Thursday, April 28, 2005 5:57 AM
To: Ciarrocca, Scott [ETHUS]; Brunel, Pascale [BuSFR]
Subject: Re: FW: AFNOR (ISO) Organization - Request

Scott
Just had a tel conversation with Pascale.
It looks like your document (FDA guidelines) may meet the AFNOR request if we are able to demonstrate in what extent we, as Gynecare organization, were able to follow up those points.
I assume those guidelines apply both for Prolift and TVT and TVT-O ?
Ideally we would need some bullets points of what Gynecare did for each of those FDA points. Would that be possible to do it ?
In addition our understanding is that this doct is only refering to one standard (ISO 10993). Is there any other standard we may refer to before releasing a product ?
Is there any other specific testings done when a product is released in EU ? It may be worthwhile to describe at least what we ve done within the CE mark and any additional testings if appropriate to demonstrate our premium quality Vs competition .

We do appreciate your support
Thanks very much
Regards
Xavier
0033664055604

-----Original Message-----
From: Ciarrocca, Scott [ETHUS] <SCiarro2@ETHUS.JNJ.com>
To: Brunel, Pascale [BuSFR] <PBRUNEL@jnjfr.jnj.com>
CC: Buchon, Xavier [ETHFR] <XBUCHON@jnjfr.jnj.com>
Sent: Wed Apr 27 17:33:18 2005
Subject: FW: AFNOR (ISO) Organization - Request

Pascale -

Please find the FDA Guidance document per Xavier's request.

Best Regards,

Scott

-----Original Message-----
From: Buchon, Xavier [ETHFR]
Sent: Wednesday, April 27, 2005 11:22 AM
To: Ciarrocca, Scott [ETHUS]
Subject: Re: AFNOR (ISO) Organization - Request

Scott i m currently off with no other email access than my blackberry till next sunday.. Could you please copy of your email Pascale Brunel who is our regulatory director for Ethicon. She has attended the Afnor meeting with me. Thanks very much. We ll be then able to discuss it on the phone with her and get back to you asap.
Thanks very much
Regards
Xavier

-----Original Message-----
From: Ciarrocca, Scott [ETHUS] <SCiarro2@ETHUS.JNJ.com>
To: Buchon, Xavier [ETHFR] <XBUCHON@jnjfr.jnj.com>
Sent: Wed Apr 27 16:51:54 2005
Subject: RE: AFNOR (ISO) Organization - Request

Xavier -

I have managed to obtain a copy of the FDA Guidance Document for Surgical Meshes. This is the document we have used to dictate the testing we have done on these materials and offers and excellent summary of what the FDA expects of companies when bringing these materials to market. Please take a look and see if this is of use. I am assuming you are not looking for our actual test data / results.

Also, I am looking for some post-release animate studies we have done. Will keep you posted.

-----Original Message-----
From: Buchon, Xavier [ETHFR]
Sent: Thursday, April 14, 2005 11:48 AM
To: Smith, Dan [ETHUS]; Ciarrocca, Scott [ETHUS]

Cc: Angelini, Laura [ETHIT]; Brunel, Pascale [BuSFR]; Damotte, Marie-Ange [ETHFR]; Evans, Paula [ETHGB]; Berthier, Ophelie [ETHFR]
Subject: AFNOR (ISO) Organization - Request
Importance: High
Sensitivity: Confidential

Dear Dan and Scott,

Over the last few months in our country, we can observe a clear awareness from the KOLs and others surgeons in regards to what is or not a good prothesis, both for SUI slings AND prolapse repair.

Under the initiative of Gynecare France, we succeed in convincing our local standards organization (AFNOR) to set-up a commission. Her goal will be to try to standardize that market in those both areas. 1st step will be a local standard and then a european one.

The 2 co-presidents for that Commission will be Pr Jacquetin (gyne) and Pr Haab (uro).

Further to our last meeting with AFNOR guys, we have been requested as others competitors to provide the following for TVT and TVT-0 as well as TVM Prolift :

* initial testings completed before releasing the products on the markets (material caracterization etc...)
* applicable standards to the previous point (clinicals, materials, test methods...)
* the way we as manufacturer, did evaluate the products on pre clinicals side as well as clinical sides (litterature analysis, animal's trials, human investigations...)

The critical point is that we would need to gather such info by April 29th...

I can imagine how challenging it might be to gather so much info by that time and really appreciate your support here as it is critical to demonstrate once more our premium quality and to have a chance to even more differenciate our products. Laura suggested us to send you that request.

If you are not able to deal with some points of that request i would really appreciate you to tell us who sould be the most appropriate person to contact with.

Thank you very much in advance for your attention and best regards

Xavier
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